

REMARKS

Claims 1, 50, 62 and 65 are hereby amended, claims 99-132 are hereby cancelled, claims 136-168 are hereby added and after entry of this response claims 1-98 and 133-168 remain pending in the present application. Applicant respectfully requests reconsideration by the Examiner in light of the following remarks.

The Examiner has rejected claims 50-52, 54, 55 and 63-66 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,800,792 (McKnight et al). The Examiner has asserted that McKnight teaches “a collagen film dressing impregnated with finely divided silver...Glutaraldehyde is disclosed as a tanning agent...Water is specified and Compression is disclosed”. The Applicant respectfully asserts that the reference cited by the Examiner does not disclose or suggest an electromatrix device wherein the protein materials, conductive materials, pharmacologically active agents and biocompatible solvents are formed into a cohesive body and compressed. Therefore, the present claims provide claim limitations that are not present in McKnight. For example, claim 50 (and the related dependent claims) claims an electromatrix device that is formed by compressing a cohesive body to remove bulk biocompatible solvent and generate additional interactive forces.

A cohesive body, as disclosed in the present application, is formed when a composition, including the protein materials and biocompatible solvents, includes the proper proportions of the protein and solvent to make such a protein/solvent composition cohesive and formable i.e. the composition prefers to stick to itself rather than other materials and is a formable body that may be formed into a desired shape or configuration. See the present application at pages 16 and 17.

Contrary to the cohesive body of the present invention, it is well known in the art

that as a protein material is gelled and/or crosslinked, the protein molecules become more ordered and fixed into position due to both physical and chemical bonds among the proteins. Through such bonding, the ability of the proteins to continue to re-organize is lost when in a gelled and/or crosslinked state, as is expected when the McKnight collagen fiber dispersion is gelled and subsequently crosslinked before compression, thereby inhibiting the protein and solvent composition from forming a cohesive body.

In the cohesive body of the present invention, the protein and solvent molecules closely interact through physical bonds and molecular forces, such as non-covalent bonding and electrostatic interactions (not substantially through chemical bonds, such as covalent bonds, as found in gels and/or crosslinked matrices), but remain substantially unset and mobile. Such interaction and the unset and mobile characteristics found among the protein and solvent molecules allows the protein-solvent material to be cohesive, formable and compressible so bulk water can be reduced during compression to form the electromatrix of the present invention. Therefore, it has been found by the Applicant that unless the protein/solvent composition has reached this well-defined cohesive, formable and compressible state and the protein and solvent molecules are properly positioned and still mobile within the cohesive body, an electromatrix material cannot be formed upon compression.

The protein molecules' ability to remain mobile in a properly solvated environment, as found in the cohesive body, and to re-organize is necessary for additional binding among the protein and solvent molecules upon compression. Generally, the compression of a cohesive body alters protein molecule conformation and their relative position within the cohesive body, thereby bringing the solvated protein molecules and their binding sites closer together to form additional bonds that would not be formed but for the mobile characteristics

maintained by the protein in the cohesive body; these mobile characteristics are not found or possible in solutions, gels or crosslinked matrices, such as the gelled and crosslinked collagen fiber dispersion of McKnight. In the present invention, the compression fixes the cohesive body into a stronger form by the additional protein binding, not possible with a gelled dispersion or crosslinked fixed gel. Therefore, it is apparent that the collagen fiber dispersion used in the McKnight reference was gelled and subsequently was subjected to covalent cross-linking from contact with a tanning agent to further strengthen and permanently set the collagen dispersion. Such gelation and cross-linking would therefore not allow the formation of a cohesive body. Hence a compressed electromatrix could not be formed.

Additionally, the cohesive body necessary to produce the protein matrix material of the present invention will generally include a surface area that is less than that of the composition or film of which it is derived to promote cohesion. See the present application at page 6, lines 4 and 5 and page 17, lines 20 and 21. The reduction in surface area from the coatable composition or film allows for the protein and solvent molecules to be of the proper proportion and position to substantially interact with each other so as to become cohesive. McKnight does not disclose a process that includes a reduction in surface area of the collagen fiber dispersion prior to compression, which is necessary to properly proportion and position the protein and solvent molecules so that they may interact with each other during compression. Therefore, McKnight does not disclose a cohesive body, which is necessary to produce an electromatrix material.

As previously suggested, the McKnight reference does not disclose or suggest the claimed intermediate material, the cohesive body. As previously mentioned, the cohesive body is necessary to formulate the compressed electromatrix product of the present invention. Without a

cohesive body, thereby providing the proper proportions and positioning of protein and solvent molecules, the compression will not produce the desired protein electromatrix material. For example, too much solvent will cause the composition to be too much like a liquid, thereby preventing the material from being cohesive, i.e. the composition will not substantially stick to itself. Alternatively, too little solvent will cause the composition to crack, shatter, break or otherwise lack cohesiveness upon efforts to form the cohesive body. Furthermore, a gelled and/or crosslinked collagen fiber dispersion, because it already a fixed structure, will also cause the composition to crack, shatter, break or otherwise lack cohesiveness upon efforts to form a cohesive body.

McKnight discloses a collagen fiber dispersion that is gelled, spread into a film, tanned (i.e. crosslinked) and subsequently dried under slight pressure to form collagen foam for dressings. See McKnight, Col. 3, lines 43-68 and Col. 4, lines 1-59. The gelling and crosslinking of the collagen fiber sets the film into a structured form, thereby causing the protein to lose its mobile capabilities and preventing the material to form an electromatrix material upon compression. Therefore, McKnight does not disclose or suggest an electromatrix material that is formed by compressing a properly prepared *intermediate material*, the cohesive body, because McKnight does not disclose or suggest the formation of a cohesive body.

As explained in the previous paragraphs the protein matrix material of the claimed invention is derived from an intermediate material, the cohesive body, that is formed prior to compression and which is not disclosed in McKnight. The collagen fiber dispersion disclosed or suggested in McKnight is gelled and subsequently crosslinked prior to compression, thereby not allowing compression to produce additional binding among the protein and solvent molecules as found when compressing a cohesive body. Therefore, McKnight fails to disclose or suggest all

the limitations of the claims of the present application. Since the limitations of the present claims are not found in the teaching of the collagen material disclosed by McKnight, Applicant respectfully requests that the rejection under 102(b) be withdrawn and that the pending claims be allowed.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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